

52. A method of feeding a ruminant, the method comprising:
providing a feed that comprises a ruminally-protected sugar alcohol; and
supplying the sugar alcohol to the abomasum of the ruminant, the sugar alcohol
effective to enhance the weight percent of total solids in milk produced by the
ruminant.
53. A method of feeding a ruminant, the method comprising:
providing a feed that comprises a ruminally-protected sugar alcohol; and
supplying the sugar alcohol to the abomasum of the ruminant, the sugar alcohol
effective to enhance the weight percent of true protein, lactose, fat, total
solids, or any combination of any of these in milk produced by the ruminant.

REMARKS

This Amendment is submitted in response to the Office Action mailed on July 16, 2001. With this Amendment, no claims are canceled; no claims are amended; and new claims 44-53 are added. Additionally, claims 15-27 stand withdrawn from consideration by the Examiner as being drawn to a non-elected invention, and claims 5-7 and 12 stand withdrawn from consideration by the Examiner as being drawn to a non-elected species. Applicant continues to traverse the election requirement as to claims 15-27, though Applicant no longer traverses the Examiner's species election requirement as between claims 5-7 and 12. Upon entry of this Amendment, the above-identified application will include claims 1-53.

Election Requirement Based On Alleged Distinctness.

In the present Office Action, the Examiner continues to rely on a prior election requirement under 35 U.S.C. §121 that the Examiner originally stated in the Office Action mailed on March 31, 2000. The Examiner's prior election requirement placed claims "1-14, 19-24, drawn to Methods of Feed Administration, classified in Class 424, Subclass 438" in Group I, placed claims

“15-18, drawn to Feed Production, classified in Class 426, Subclass 54” in Group II, and placed claims “25-27, drawn to Feed, classified in Class 14, Subclass 738” in Group III. For the reasons set forth in the Amendment filed on April 10, 2001 in the above-identified application, Applicant continues to believe that the Examiner’s restriction between the invention of the above-identified application, as defined in the claims that the Examiner has placed in Groups I, II, and III, is improper and should be withdrawn. Therefore, Applicant continues to traverse the Examiner’s election requirement between the invention of the above-identified application, as defined in the claims the Examiner has placed in Groups I, II, and III, and requests reconsideration and withdrawal of this election requirement.

Provisional Double Patenting Rejection Based Upon Claims 1-40 of Application S/N 09/338,314.

In the present Office Action, the Examiner provisionally rejected claims 1 and 2 “under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of co-pending Application No. 09/338,314.” In support of this obviousness-type double patenting rejection, the Examiner stated: “Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are obvious variants of each other.”

As noted by the Examiner, this is a provisional rejection. Applicant is prepared to address this provisional rejection by taking appropriate action upon any grant of co-pending Application No. 09/338,314 as a U.S. Patent and/or allowance of the present application, save for this provisional double patenting rejection. These comments are believed to adequately address the Examiner’s provisional rejection of claims 1-2 based upon claims 1-40 of co-pending Application S/N 09/338,314.

Double Patenting Rejection Based Upon Claims 1-9 of U.S. Patent No. 5,503,112.

In the present Office Action, the Examiner rejected claims 1, 9, 10, and 13 under the judicially created doctrine of obviousness-type double patenting as allegedly “being unpatentable over claims 1-9 of U.S. Patent No. 5,503,112.” In support of this rejection, the Examiner stated:

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims the instant method steps: feeding sugar alcohol; since up to 500 g are fed, some would get to the abomasum of instant claim 10 method.

Despite the Examiner’s comments, claims 1-9 of U.S. Patent No. 5,503,112 do not teach, suggest, disclose, or make obvious the invention of the above-identified application, as defined in claims 1, 9, 10, and 13.

Claims 1 and 10 of the present application each require that sugar alcohol be supplied to the abomasum of the ruminant. The Examiner alleges that U.S. Patent No. 5,503,112 discloses feeding of sugar alcohol in an amount “up to 500 g.” However, Applicant finds no such disclosure of sugar alcohol feeding, in either claims 1-9 of U.S. Patent No. 5,503,112 or, for that matter, anywhere in the text of U.S. Patent No. 5,503,112. Consequently, in view of this non-existent sugar alcohol disclosure in claims 1-9 of U.S. Patent No. 5,503,112, it is an impossibility for claims 1-9 of U.S. Patent No. 5,503,112 to render claims 1 and 10 of the above-identified application obvious.

Claims 1 and 10 are believed allowable. Claim 9 is also believed allowable, since claim 9 depends from allowable claim 1. Likewise, claim 13 is believed allowable, since claim 13 depends from allowable claim 10. Consequently, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1, 9, 10, and 13 under the judicially created doctrine of obviousness-type double patenting based upon claims 1-9 of U.S. Patent No. 5,503,112 and that claims 1, 9, 10, and 13 of the above-identified application be allowed.

Claim Rejections Under the Enablement Requirement of the First Paragraph of 35 U.S.C. §112.

In the Office Action, the Examiner rejected claims 1, 8-10, 29-32, and 34-37 under the first paragraph of 35 U.S.C. §112 as allegedly “containing subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.” Despite the Examiner’s comments, claims 1, 8-10, 29-32, and 34-37 are each in fact enabled by the specification of the above-identified application in accordance with the first paragraph of 35 U.S.C. § 112.

In support of this rejection, the Examiner stated:

The rejection of record stands -- only limited means are disclosed to provide production component effective enhancement

Later in the Office Action and apparently in support of this enablement rejection, the Examiner additionally stated:

Applicants arguments and explanations have resulted in withdrawal of some rejections; however, the open language of claim 1 of supplying the sugar to the abomasum is seen as suggesting means beyond those presented in the specification.

Again, despite the Examiner’s comments, claims 1, 8-10, 29-32, and 34-37 are each in fact enabled by the specification of the above-identified application in accordance with the first paragraph of 35 U.S.C. §112.

The Examiner’s claim rejection under the first paragraph of 35 U.S.C. §112 is concerned with the enablement requirement of the first paragraph of 35 U.S.C. §112. The middle portion of the first paragraph of 35 U.S.C. §112 addresses the enablement requirement: “The specification shall contain a written description . . . of the manner and process of making and using . . . [the claimed invention] . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use it.” The enablement requirement is thus concerned with whether the specification disclosure teaches how to make and use the invention that is defined in the claims.

Thus, the enablement issue is concerned with whether the specification disclosure teaches how to make and use the invention that is defined in the claims. If the specification disclosure contains this teaching, the claims must be concerned to be enabling under the first paragraph of §112 unless the Examiner explains why the Examiner doubts the truth or accuracy of

any enabling statement in the disclosure. Otherwise stated, the Examiner has the initial burden of “setting forth a reasonable factual explanation, based on the record as a whole, as to *why* the Examiner believes that the scope of protection provided by the claims is not adequately enabled by the description of the invention that is defined in the claims.” In re Wright, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). Furthermore, under Wright, the Examiner must back up assertions controverting the truth and accuracy of enabling statements with acceptable evidence or reasoning as to why the enabling statement is believed untrue or inaccurate.

Applicants assert that the disclosure of the above-identified application does in fact enable claims 1, 8-10, 29-32, and 34-37. Applicants believe that claims 1, 8-10, 29-32, and 34-37 are each allowable since the disclosure of the above-identified application does enable claims 1, 8-10, 29-32, and 34-37 and is of at least the same breadth as claims 1, 8-10, 29-32, and 34-37. Claims 1 and 10 each call for “a feed that comprises a sugar alcohol,” along with “supplying the sugar alcohol to the abomasum of the ruminant.” Claim 1 is defined in terms of a “method of enhancing milk component production in a ruminant,” whereas claim 10 is defined in terms of a “method of feeding a ruminant,” while stating: “the sugar alcohol effective to enhance milk component production by the ruminant.”

Claim 8 depends from independent claim 1 and defines “enhancing milk component production” in terms of “enhancing the weight percent of true protein, the weight percent of fat, the weight percent of lactose, the weight percent of total solids, or any combination of these in milk produced by the ruminant.” Claim 9 depends from independent claim 1 and defines the sugar alcohol of claim 1 as “D-arabinitol, L-arabinitol, erythritol, galactitol, inositol, mannitol, perseitol, ribitol, sorbitol, xylitol, glycerol, or any combination of these.” Next, claims 29 and 34 depend from independent claims 1 and 10, respectively, and define “enhancing milk component production” in terms of “enhancing the weight percent of true protein in milk produced by the ruminant.” Likewise, claims 30 and 35 depend from independent claims 1 and 10, respectively, and define “enhancing milk component production” in terms of “enhancing the weight percent of lactose in milk produced by the ruminant.” Next, claims 31 and 36 depend from independent claims 1 and 10, respectively,

and define “enhancing milk component production” in terms of “enhancing the weight percent of fat in milk produced by the ruminant.” Finally, claims 32 and 37 depend from independent claims 1 and 10, respectively, and define “enhancing milk component production” in terms of “enhancing the weight percent of total solids in milk produced by the ruminant.”

The Examiner’s two comments in support of the enablement rejection:

1. only limited means are disclosed to provide production component effective enhancement.
2. the open language of claim 1 of supplying the sugar to the abomasum is seen as suggesting means beyond those presented in the specification.

The Examiner seems to be primarily questioning the breadth of the enabling disclosure in relation to the invention of the above-identified application, as defined in claims 1, 8-10, 29-32, and 34-37. Applicant notes that the Examiner suggests there are allegedly other techniques available for supplying sugar alcohol to the abomasum, though the Examiner does not say anything about what these other alleged potential techniques are. Furthermore, even if other techniques are available beyond those specifically disclosed in the above-identified application, this fact does not necessarily mean that the invention defined in claims 1, 8-10, 29-32, and 34-37 is broader than the disclosure of the above-identified application. In fact, upon detailed examination of the above-identified application, it is clear that the disclosure is at least as broad as the invention of the above-identified application, as defined in claims 1, 8-10, 29-32, and 34-37.

In this regard, the above-identified application generally discloses a method for enhancing the concentration of milk components, including fat, true protein, lactose, and total solids, in milk produced by ruminants and characterizes this method in terms of feeding ruminants a feed composition that includes at least a sugar alcohol component, where the sugar alcohol component may be directly introduced into the abomasum of the ruminant or may be ruminally-protected and orally fed to the ruminant:

The method of the present invention entails feeding ruminants the feed composition that includes at least a sugar alcohol component,

where the sugar alcohol component is either (1) introduced directly into the abomasum of the ruminant or (2) is protected from alteration by the rumen and is orally fed to the ruminant.

(Page 2, line 23, through page 3, line 2, of the above-identified application). The application provides a specific definition of the "sugar alcohol" term and thereafter lists, non-exhaustively, a number of specific examples of suitable sugar alcohols:

As used herein, sugar alcohol is defined as a polyhydric alcohol formed by the reduction of the carbonyl group of a sugar to a hydroxyl group, with no more than one hydroxy group being attached to any one carbon atom of the sugar alcohol. Three preferred examples of sugar alcohols that may be used in practicing the present invention include sorbitol, xylitol, and glycerol. Some additional non-exhaustive examples of other sugar alcohols that may be used in practicing the present invention include adonitol; allitol; altritol (D-altritol, L-altritol, and D,L altritol); arabinitol (D-arabinitol, L-arabinitol, and D,L arabinitol); dulcitol (a.k.a galactitol); erythritol; galaxitol; glucitol (D-glucitol, L-glucitol, and D,L glucitol); iditol (D-iditol and L-iditol); inositol; isomalt; lactitol; maltitol; mannitol (D-mannitol, L-mannitol, and D,L mannitol); perseitol; ribitol; rhamnitol; and threitol (D-threitol, L-threitol, and D,L threitol). These sugar alcohols may be provided individually or in any combination to the ruminant.

(Page 3, lines 15-27, of the above-identified application). The non-exhaustive list of sugars recited in the above-identified application includes, among others, all of the sugar alcohols that are defined in claim 9.

The application first discusses the general technique of directly introducing sugar alcohol into the abomasum:

It has been discovered that if a sugar alcohol is introduced directly in the abomasum of a ruminant, the total solids content of milk produced by the ruminant is typically increased. Additionally, this direct introduction of sugar alcohol into the abomasum also causes the weight percent of fat, the weight percent of true protein, and/or the weight percent of lactose in the milk to increase. For example, when abomasally infusing sugar alcohols, such as sorbitol, xylitol, and glycerol, the solids content of milk produced by the ruminant,

particularly the fat content and the true protein content of the milk, typically increases.

(Page 3, lines 3-10, of the above-identified application). The above-identified application then goes on to exhaustively discuss the direct approach to introducing sugar alcohol into the abomasum in accordance with the present invention, such as at page 4, lines 6-17; page 7, line 24 through page 10, line 23, of the above-identified application. Additionally, a variety of different examples for directly introducing different sugar alcohols into the abomasum in accordance with the present invention are provided in Examples 1-6 that extend from page 13, line 6, through page 20, line 8, of the above-identified application.

Next, the above-identified application describes another broad alternative approach to supplying sugar alcohol to the abomasum, where this approach entails orally supplying sugar alcohol to the ruminant, with the sugar alcohol being rendered ruminally-protected:

As an alternative to infusing sugar alcohol into the abomasum of the ruminant, the sugar alcohol could be included as a component of feed that is orally fed to the ruminant. When this approach is taken, it is necessary that the orally-introduced feed composition, or at least the sugar alcohol component of the orally-introduced feed composition, be treated or otherwise prepared to render the sugar alcohol ruminally-protected. As used herein, the term "ruminally-protected" means protected from alternation during passage through the rumen.

(Page 4, lines 18-24, of the above-identified application). As with the approach to directly supplying sugar alcohol to the abomasum, extensive and detailed discussions about orally supplying ruminally-protected sugar alcohol to the abomasum are provided, such as at page 4, line 25, through page 7, line 23, of the above-identified application.

Thus, the above-identified application does detail broad approaches to supplying sugar alcohol, as a feed component, to the abomasum of the ruminant, where the sugar alcohol is described as being effective to enhance production of different milk components. Furthermore, the above-identified application does specifically describe the different sugar alcohols listed in claim 9 as part of this methodology. Likewise, the above-identified application does specifically describe this broad technique in terms of enhancing production of different milk components, such as each

and every one of the milk components that are defined in claim 8, as well as, in claims 29-32 and 34-37. Clearly, despite the Examiner's allegations about "limited means," the above-identified application instead discloses the claimed invention in terms that are at least as broad as the terms employed in claims 1, 8-10, 29-32 and 34-37 that define techniques for supplying sugar alcohol to the abomasum of the ruminant as part of a feed, where the sugar alcohol is effective to enhance milk component production by the ruminant.

The mere fact that the Examiner could potentially envision additional approaches to supplying sugar alcohol to the abomasum of the ruminant while maintaining the effectiveness of the sugar alcohol for enhancing milk component production beyond the broad approaches described in this application, does not diminish the clear and present enablement that the above-identified application provides for the present invention, as defined in claims 1, 8-10, 29-32, and 34-37. Ultimately, the Examiner has not born the Examiner's initial burden of "setting forth a reasonable factual explanation, based on the record as a whole, as to *why* the Examiner believes that the scope of protection provided by the claims is not adequately enabled by the description of the invention that is defined in the claims," as required by Wright. Consequently, despite the Examiner's allegations, Applicant continues to believe that the invention of the above-identified application, as defined in claims 1, 8-10, 29-32, and 34-37, is in fact enabled under the first paragraph 35 U.S.C. §112 and is allowable.

Claims 1, 8-10, 29-32, and 34-37 are believed allowable. Consequently, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1, 8-10, 29-32, and 34-37 under the first paragraph of 35 U.S.C. §112 and that claims 1, 8-10, 29-32, and 34-37 be allowed.

Rejections Under 35 U.S.C. §102 Based Upon the Merensalmi Patent.

In the Office Action, the Examiner rejected claims 1-3, 9-11, 13, 28, 33, and 38-43 under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 4,127,676 to Merensalmi (the "Merensalmi patent"). In support of this rejection, the Examiner stated:

The instant (claim 1) method constitutes the step of: providing a feed with sugar alcohol, and supplying to the abomasum. Merensalmi adds sugar alcohols to feed (lines 5-15, col. 2) and supplies to the abomasum--since the sugar alcohol is intact through the fumen [sic] (line 53-68; col. 2-lines 30-33, col. 3). Milk yield, therefore the components of the milk (unspecified) by applicant's claims are increased (claim 1 of Merensalmi). Over 90% of the sugar alcohol is available to the abomasum, at 2 hours (col. 3, top, Example 1).

Despite the Examiner's comments, the Merensalmi patent does not in fact disclose each and every feature required by claims 1-3, 9-11, 13, 28, 33, and 38-43. Consequently, the Merensalmi patent does not anticipate any of claims 1-3, 9-11, 13, 28, 33, or 38-43.

Claims 1 and 10 each require that sugar alcohol be supplied to the abomasum of the ruminant. Claims 2 and 11, that depend from claims 1 and 10, respectively, each require: "protecting the sugar alcohol from significant alteration in the rumen of the ruminant," while claim 3, which depends from claim 2, further requires: "protecting the sugar alcohol from substantial alteration in the rumen of the ruminant." Additionally, claims 28 and 33, that depend from claims 1 and 10, respectively, specify: "the sugar alcohol is ruminally-protected." Finally, claims 38-40 and claims 41-43, which depend from claims 2 and 11, respectively, each further define "protecting the sugar alcohol from significant alteration in the rumen of the ruminant" in terms of different numerical weight percents of orally ingested sugar alcohol that "arrive unaltered, as sugar alcohol, in the abomasum of the ruminant after passing through the rumen of the ruminant."

The Examiner replies upon *in vitro* test results that are disclosed in the Merensalmi patent for the central statement of the Examiner's allegations in support of this §102(b) rejection based upon the Merensalmi patent:

"Merensalmi adds sugar alcohols to feed (lines 5-15, col. 2) and supplies to the abomasum--since the sugar alcohol is intact through the fumen [sic] (line 53-68; col. 2-lines 30-33, col. 3)."

However, as explained to the present Examiner in another application concerning sugar alcohol feeding, the Merensalmi patent only describes *in vitro* sugar alcohol testing where the *in vitro* sugar alcohol testing only addresses the effect of "rumen fluid" on individual sugar alcohols during the *in*

vitro rumen fluid testing. (Col. 2, line 59, through col. 3, line 11 of the Merensalmi patent). No details about the conditions of the rumen fluid and no details about the *in vitro* test conditions, other than the mere presence of the rumen fluid and of the individual sugar alcohols, is provided in the Merensalmi patent with regard to this *in vitro* testing regimen of Merensalmi Example 1.

The Merensalmi patent does allege a number of *conclusions* about *in vivo* degradation of sugar alcohol mixtures in the rumen of a ruminant. (Col. 2, lines 53-57; col. 3, lines 13-37; and col. 4, lines 45-47 of the Merensalmi patent). However, these conclusions are merely speculative conclusions that are entirely based upon the presumption that the *in vitro* rumen fluid testing of Example 1 (and its unstated test conditions) transfers, with no significant change in results, to an *in vivo* environment. This is a big leap of faith, especially considering that the inventors of the Merensalmi patent provided little if anything in the way of support for this presumption. Consequently, this presumptive conclusion by the inventors of the Merensalmi patent is speculative at best and does not amount to a disclosure that sugar alcohol would in fact pass through the rumen under *in vivo* conditions without major metabolism of the sugar alcohol originally provided to the ruminant.

The Examiner has previously agreed with the above comments about the speculative nature of the sugar alcohol passage conclusions of the Merensalmi patent under *in vivo* conditions. This speculative nature of the sugar alcohol passage conclusions in the Merensalmi patent consequently illustrates the failure of the Merensalmi patent to actually disclose supplying sugar alcohol to the abomasum, as required by each and every one of claims 1-3, 9-11, 13, 28, 33, and 38-43. Consequently, based upon this discussion alone, claims 1-3, 9-11, 13, 28, 33, and 38-43 are each believed allowable over the Examiner's §02 rejection based upon the Merensalmi patent.

Furthermore, as noted, claims 2 and 11 require "protecting the sugar alcohol from significant alteration in the rumen of the ruminant," while claim 3 requires "protecting the sugar alcohol from substantial alteration in the rumen of the ruminant." Additionally, claims 28 and 33 require the sugar alcohol to be "ruminally-protected," which means that the sugar alcohol is "protected from alteration during passage through the rumen." (Page 4, lines 23-24 of the above-

identified application). None of these aspects of claims 2-3, 11, 28, or 33 are disclosed by the Merensalmi patent.

Indeed, as noted above, the Merensalmi patent merely discloses exposure of sugar alcohol to rumen fluid under *in vitro* testing conditions. However, the mere disclosure of this *in vitro* testing (outside the rumen, by definition) does not amount to a disclosure of *in vivo* results that would be required for disclosing the features of claims phrased in terms of protecting sugar alcohol from varying degrees of alteration in the rumen of the ruminant. Indeed, the most glaring defect in the Examiner's rejection based upon the Merensalmi patent is the failure to recognize that the *in vitro* testing of sugar alcohol in the rumen fluid occurred on unprotected sugar alcohol. There is no disclosure whatsoever in the Merensalmi patent about the sugar alcohol being subjected to some type of a rumen-protective treatment prior to the disclosed *in vitro* testing in the rumen fluid.

Thus, rather than disclosing how protected sugar alcohol performs in the rumen fluid under the *in vitro* conditions of the Merensalmi patent, the Merensalmi patent instead discloses the effect of rumen fluid contact, under *in vitro* conditions, on non-ruminally-protected sugar alcohol. In essence, the *in vitro* test results of the Merensalmi patent are provided in an attempt, albeit highly speculative, to demonstrate that protection of sugar alcohol is not needed while allowing some percentage of sugar alcohol to pass through the rumen and into the abomasum. Again, this attempt by the Merensalmi patent is incomplete and is speculative at best, since the Merensalmi patent only discloses the use of "rumen fluid" in this *in vitro* discussion and does not provide any details whatsoever about the conditions of the rumen fluid or about the conditions of the *in vitro* testing.

Consequently, for this additional reason, the Merensalmi patent fails to disclose the sugar alcohol protection feature defined in claims 2, 3, and 11 and fails to disclose the "ruminally-protected" aspect of the sugar alcohol that is required by claims 28 and 33. Consequently, for this additional reason, claims 2, 3, 28, and 33 are believed allowable. Furthermore, claims 38-40 and 41-43 are each believed allowable, since claims 38-40 depend from allowable claim 2 and since claims 41-43 depend from allowable claim 11.

Next, we again consider that claims 1 and 10 each concern enhancing milk component production by supplying a sugar alcohol to the abomasum of the ruminant. The Merensalmi patent generally discloses a fodder additive for cows that may increase milk production of cows. However, the Merensalmi patent does not disclose anything about the fodder additive enhancing milk **component** concentrations in produced milk. In fact, Applicant directs the Examiner's attention to column 3, line 64, to column 4, line 2, of the Merensalmi patent where a net **decrease** in the fat percentage in milk produced by test animals is observed upon start of a sugar alcohol feeding regimen. Additionally, while the Merensalmi patent does disclose an increase in blood sugar levels during test feeding of a test animal, this increase is merely a recovery to levels present at the onset of the test feeding regimen prior to introduction of the sugar alcohol and no corresponding enhancement in milk component concentrations is disclosed. Furthermore, as stated above, this recovery of blood sugar levels is not disclosed to have increased milk component concentrations in produced milk. Instead, the Merensalmi patent discloses only a decrease in fat concentrations in produced milk in reaction to the blood sugar level recovery.

Next, claim 8 reads as follows:

8. *The method of claim 1 wherein enhancing milk component production comprises enhancing the weight percent of true protein, the weight percent of fat, the weight percent of lactose, the weight percent of total solids, or any combination of these in milk produced by the ruminant.*

Claim 8 further defines that enhancing milk component production in accordance with the present invention includes enhancing the weight percent of true protein, fat, lactose, and/or total solids in milk that is produced by the ruminant.

The Merensalmi patent does not teach or disclose anything about an increase in the weight percent of true protein, fat, lactose, and/or total solids occurring in the milk produced by the test animals. Additionally, Applicant directs the Examiner's attention to column 3, lines 64-68, that disclose a **decrease** in the fat percentage in milk produced by the test animals of the Merensalmi patent.

The foregoing comments demonstrate that the Merensalmi patent does not disclose each of the features required by claim 8. Consequently, the Merensalmi patent does not anticipate claim 8 of the above-identified application.

Claims 29 and 34 read as follows:

29. The method of claim 1 wherein enhancing milk component production comprises enhancing the weight percent of true protein in milk produced by the ruminant.

34. The method of claim 10 wherein enhancing milk component production comprises enhancing the weight percent of true protein in milk produced by the ruminant.

Claims 29 and 34 further define that milk **component** production enhancement in terms of enhancing the weight percent of true protein in milk that is produced by the ruminant. The Merensalmi patent does not teach or disclose anything about an increase in the weight percent of true protein occurring in the milk produced by the test animals. Furthermore, the Examiner has never even alleged that the Merensalmi patent discloses anything about increasing the concentration of true protein in milk produced by the test animals.

The foregoing comments demonstrate that the Merensalmi patent does not disclose each of the features required by claims 29 and 34. Consequently, the Merensalmi patent does not anticipate either claim 29 or claim 34 of the above-identified application.

Claims 30 and 35 read as follows:

30. The method of claim 1 wherein enhancing milk component production comprises enhancing the weight percent of lactose in milk produced by the ruminant.

35. The method of claim 10 wherein enhancing milk component production comprises enhancing the weight percent of lactose in milk produced by the ruminant.

Claims 30 and 35 further define that milk **component** production enhancement in terms of enhancing the weight percent of lactose in milk that is produced by the ruminant. The Merensalmi patent does not teach or disclose anything about an increase in the weight percent of lactose

occurring in the milk produced by the test animals. Furthermore, the Examiner has never even alleged that the Merensalmi patent discloses anything about increasing the concentration of lactose in milk produced by the test animals.

The foregoing comments demonstrate that the Merensalmi patent does not disclose each of the features required by claims 30 and 35. Consequently, the Merensalmi patent does not anticipate either claim 30 or claim 35 of the above-identified application.

Claims 31 and 36 read as follows:

31. The method of claim 1 wherein enhancing milk component production comprises enhancing the weight percent of fat in milk produced by the ruminant.

36. The method of claim 10 wherein enhancing milk component production comprises enhancing the weight percent of fat in milk produced by the ruminant.

Claims 31 and 36 further define that milk **component** production enhancement in terms of enhancing the weight percent of fat in milk that is produced by the ruminant. The Merensalmi patent does not teach or disclose anything about an increase in the weight percent of fat occurring in the milk produced by the test animals. Instead, at column 3, lines 64-68, the Merensalmi patent actually discloses a **decrease** in the fat percentage in milk produced by the test animals of the Merensalmi patent. Furthermore, the Examiner has never even alleged that the Merensalmi patent discloses anything about increasing the concentration of fat in milk produced by the test animals.

The foregoing comments demonstrate that the Merensalmi patent does not disclose each of the features required by claims 31 and 36. Consequently, the Merensalmi patent does not anticipate either claim 31 or claim 36 of the above-identified application.

Claims 32 and 37 read as follows:

32. The method of claim 1 wherein enhancing milk component production comprises enhancing the weight percent of total solids in milk produced by the ruminant.

37. The method of claim 10 wherein enhancing milk component production comprises enhancing the weight percent of total solids in milk produced by the ruminant.

Claims 32 and 37 further define that milk **component** production enhancement in terms of enhancing the weight percent of total solids in milk that is produced by the ruminant. The Merensalmi patent does not teach or disclose anything about an increase in the weight percent of total solids occurring in the milk produced by the test animals. Furthermore, the Examiner has never even alleged that the Merensalmi patent discloses anything about increasing the concentration of total solids in milk produced by the test animals.

The foregoing comments demonstrate that the Merensalmi patent does not disclose each of the features required by claims 32 and 37. Consequently, the Merensalmi patent does not anticipate either claim 32 or claim 37 of the above-identified application.

Claims 1-3, 10-11, 28, and 33 are each believed allowable for the reasons provided above. Claims 2-3, 11, 28, and 33 are also believed allowable for an additional reason, since claims 2-3 and 28 each depend from allowable claim 1, and since claims 11 and 33 each depend from allowable claim 10. Furthermore, claims 9, 13, and 38-43 are believed allowable, since claims 9 and 38-43 each depend from allowable claim 1, and since claims 13 and 41-43 each depend from allowable claim 1. Furthermore, claims 38-43 are believed allowable for an additional reason, since claims 38-40 each depend from allowable claim 2, while claims 41-43 each depend from allowable claim 11. Consequently, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1-3, 9-11, 13, 28, 33, and 38-43 under 35 U.S.C. §102(b) based upon the Merensalmi patent and that claims 1-3, 9-11, 13, 28, 33, and 38-43 each be allowed.

Claim Rejections Under 35 U.S.C. §103.

In the Office Action, the Examiner rejected claims 1-4, 8-11, 13-14, 29, 33, and 38-43 under 35 U.S.C. §103(a) as allegedly “being unpatentable over” the Merensalmi patent in view of U.S. Patent No. 3,959,493 to Baalsrud (subsequently referred to as the “Baalsrud patent”) and the

single page Remond '86 abstract, the single page Makinen abstract, or the single page Khalili abstract. In support of the rejection, the Examiner stated:

The rejection of record is maintained, with embellishments. Merensalmi provides an active ingredient sugar alcohols, which need to get past the rumen (col. 1, line 57-line 11, col. 2); some degradation occurs (example 1). Baalsrud, and others provide rumor [sic] by pass means to deliver active substances. One of ordinary skill in the art of feeding dairy cows would find it obvious to use a by-pass form to deliver, intact, a desired nutrient, in order to most efficiently concentrate the required amount of nutrient sources within the limited capabilities of a high producing dairy cow to accept, in order to maximize production. Merensalmi points to this problem, in 1978. It's intensified now. Khalili, Makinen and Remono also show it was known t [sic] advantageously feed dairy cows sugar alcohols.

Despite the Examiner's comments, the Merensalmi patent, the Baalsrud patent, the Remond abstract, the Makinen abstract, and the Khalili abstract, either separately or in combination, do not teach, suggest, disclose, or render obvious the invention of the above-identified application, as defined in claims 1-4, 8-11, 13-14, 28, 33, or 38-43.

As a summary, the Examiner's §103 rejection is flawed in several different ways. First, the Examiner's primary reference, the Merensalmi patent, does not actually teach that protection of sugar alcohol is beneficial or needed, since the Merensalmi patent actually discloses testing of unprotected sugar alcohol in the *in vitro* rumen fluid procedure addressed in Examples 1 and 2 of the Merensalmi patent. Consequently, the Merensalmi patent actually teaches away from the Examiner's suggested combination of the Merensalmi, Baalsrud, Remond, Makinen, and Khalili details. Secondly, like the Merensalmi patent, the Baalsrud patent actually-only concerns-overall milk production enhancement, as opposed to enhancing production of individual milk components.

Also, the Remond abstract that the Examiner relies upon is entitled "Effects of Feeding Sorbitol on Milk Yield and Blood Characteristics in Dairy Cows in Early Lactation," but does not actually disclose what these alleged effects are, since the Remond abstract does not even provide a summary or any details about what these effects of feeding sorbitol may be. Furthermore, the Makinen abstract does not disclose any protection of sugar alcohols and in fact discloses that

feeding of unprotected sugar alcohol has no significant effect upon a variety of different milk perimeters, such as protein, glucose, and various minerals. Finally, the Khalili abstract does not disclose anything about feeding of protected sugar alcohol and furthermore states that the addition of “glycerol did not have any effect on . . . milk yield or milk compn.” Thus, without even going any further into the details of the Examiner’s rejection, it is clear that the Examiner’s rejection of claims 1-4, 8-11, 13-14, 28, 33, and 38-43 under 35 U.S.C. §103(a) based upon the Merensalmi patent, the Baalsrud patent, the Remond abstract, the Makinen abstract, and the Khalili abstract is doomed to failure.

As noted previously in regard to the Examiner’s §102 rejection based upon the Merensalmi patent, claims 1 and 10 require supplying “sugar alcohol to the abomasum of the ruminant.” Claim 1 requires this in the course of “enhancing milk component production” in the ruminant, while claim 10 states that the sugar alcohol is “effective to enhance milk component production by the ruminant.” Claims 2-4 and 11 further supplement details of claims 1 and 10, respectively, by further defining “protecting the sugar alcohol” from differing degrees of “alteration in the rumen of the ruminant.” Also, claims 38-40 and 41-43 further define the “protecting the sugar alcohol from alteration in the rumen of the ruminant” aspect of claims 2 and 11, respectively. Finally, claims 28 and 33 specify that the sugar alcohol of claims 1 and 10, respectively, is “ruminally-protected.”

As established above with regard to the Examiner’s §102 rejection based upon the Merensalmi patent, the Merensalmi patent does not disclose supplying sugar alcohol to the abomasum. Instead, the Merensalmi patent, based upon *in vitro* testing of sugar alcohol in rumen fluid under unspecified *in vitro* conditions, speculatively concludes that *in vivo* feeding of sugar alcohol to ruminants would mirror the rumen fluid test results of the *in vitro* procedure. Additionally, as pointed out above, only unprotected sugar alcohol testing and feeding are disclosed in the Merensalmi patent.

In an effort to buttress the aspects of the present invention that are missing from the Merensalmi patent, the Examiner relies upon the Baalsrud patent for allegedly providing rumen bypass means “to deliver active substances:”

One of ordinary skill in the art of feeding dairy cows would find it obvious to use a by-pass form to deliver, intact, a desired nutrient, in order to most efficiently concentrate the required amount of nutrient sources within the limited capabilities of a high producing dairy cow to accept, in order to maximize production.

However, by virtue of speculating that unprotected sugar alcohol may be fed (based on the unprotected rumen fluid, *in vitro* testing of Examples 1 and 2), the Merensalmi patent actually teaches away from any such need for, or incorporation of, the protected Baalsrud substance. That is, the Merensalmi patent, though based only upon *in vitro* test results, actually suggests that protection, such as the alleged Baalsrud ruminal-protection, is not needed or desirable to attain enhanced milk production yields.

As noted, the Examiner relies upon Baalsrud in support of the alleged obviousness of using “a by-pass form to deliver, intact, a desired nutrient in order to most effectively concentrate the required amount of nutrient sources within the limited capabilities of a high producing cow to accept, in order to maximize production.” The Examiner characterizes this allegation as pointing to a problem and further alleges: “Merensalmi points to this problem, in 1978.” However, Merensalmi did not in fact point to this problem. Instead, as noted above, Merensalmi relied on the results of *in vitro* testing using unprotected sugar alcohol as Merensalmi’s basis for speculatively concluding that unprotected sugar alcohol *would* allegedly pass through the rumen in significant quantities in an unprotected form.

Thus, rather than pointing “to this problem,” as the Examiner alleges, Merensalmi actually points away from this problem. Consequently, any attempt to combine the alleged ruminal protection of the Baalsrud patent with the feeding approach advanced by the Merensalmi patent would destroy an important and intended, though believed erroneous by Applicant, function of feeding unprotected “plain” sugar alcohol to ruminants in relatively large quantities for milk

production purposes. Thus, for this additional strong reason, the Examiner's alleged combination of details from the Baalsrud patent with details of the Merensalmi patent fails to establish that the invention of the above-identified application, as defined in claims 1-4, 8-11, 13-14, 28, 33, and 38-43 is either obvious, taught, or suggested by the Merensalmi patent or the Baalsrud patent, either separately or in combination.

Furthermore, the Examiner's reliance upon the Remond, Makinen, and Khalili single page abstracts adds nothing to the Examiner's alleged combination of the Baalsrud and Merensalmi patents. The Examiner alleges that the Remond, Makinen, and Khalili single page abstracts "show it was known to advantageously feed dairy cows sugar alcohols." However, mere feeding of sugar alcohols to dairy cows, without more, adds nothing to the Examiner's reliance upon the Merensalmi and Baalsrud patents. This reliance on the Remond, Makinen, and Khalili references adds nothing: the Remond reference does not actually disclose anything about the effects of feeding sorbitol; the Makinen abstract discloses that feeding of unprotected sugar alcohols has no effect on the milk component parameters, such as protein, glucose and various minerals; and the Khalili reference discloses that the addition of glycerol "did not have any effect on *milk yield or milk compn.*" Furthermore, the Remond, Makinen, and Khalili abstracts do not concern the sugar alcohol protection required by claims 2-4, 11, and 38-43 and do not concerns the "ruminally-protected" requirement of claims 28 and 33 for the sugar alcohol, since none of the Remond, Makinen, or Khalili single page abstracts address anything other than unprotected sugar alcohol, like the sugar alcohol of the Merensalmi patent.

Finally, claim 1 defines a method of "enhancing milk component production in a ruminant," whereas claim 10 requires that the sugar alcohol be "effective to enhance milk component production by the ruminant." As noted above, the Merensalmi patent does not teach or disclose anything about enhancement of milk component production and, consequently, does not disclose anything about enhancing production of true protein, fat, total solids, or any combination of these. The Baalsrud patent does not remedy this failure of the Merensalmi patent, since the Baalsrud patent does not address sugar alcohol. Instead, the Baalsrud patent generally talks about the possibility of

ruminally protecting carbohydrates. However, the Baalsrud patent does not address rumen protection of carbohydrates in relation to milk **component** production enhancement. Instead, the Baalsrud patent, like the Merensalmi patent, only concerns overall milk production enhancement. Furthermore, as noted above, the Remond, Makinen, and Khalili abstracts do not address protection of sugar alcohols and, likewise, do not teach, suggest, or disclose feeding of sugar alcohols as an effective technique for increasing milk **component** production. Consequently, even when the disclosures of the Baalsrud patent, the Merensalmi patent, and the Remond, Makinen, and Khalili abstracts are considered, either separately or in combination, the net result is no disclosure, no teaching, and no suggestion about any milk **component** production enhancement, as required by claims 1 and 10.

The Merensalmi patent, the Baalsrud patent, the Remond abstract, the Makinen abstract, and the Khalili abstract, either separately or in combination, do not teach suggest, or disclose the invention of the above-identified application, as defined in claims 1-4, 8-11, 13-14, 28, 33, and 38-43. Consequently, claims 1-4, 8-11, 13-14, 28, 33, and 38-43 are believed allowable despite the Examiner's rejection of these claims under §103 based upon the Merensalmi and Baalsrud patents and the Remond, the Makinen, and the Khalili abstracts.

Claims 1-4, 8-11, 13-14, 28, 33, and 38-43 are each believed allowable. Claims 2-4, 8-9, 28, and 38-40 are also believed allowable for an additional reason, since claims 2-4, 8-9, 28, and 38-41 each depend from independent claim 1. Likewise, claims 11, 13, 33, and 40-43 are each also believed allowable for an additional reason, since claims 11, 13-14, 33, and 41-43 each depend from allowable claim 10. Likewise, claims 38-40 and 41-43 are each believed allowable for an additional reason, since claims 38-40 and claims 41-43, respectively, depend from allowable claims 2 and 11. Consequently, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1-4, 8-11, 13-14, 28, 33, and 38-43 under 35 U.S.C. §103 based upon the Merensalmi patent, the Baalsrud patent, the Remond abstract, the Makinen abstract, and the Khalili abstract and that claims 1-4, 8-11, 13-14, 28, 33, and 38-43 be allowed.

New Claims Added by Applicant.

Applicant has added new claims 44-53, as indicated above. Support for new claims 44-53 is believed to exist in the above-identified application. Applicant respectfully requests consideration and allowance of new claims 44-53.


CONCLUSION

Claims 1-4, 8-11, 13-14, and 28-53 are each believed allowable. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw the rejections of claims 1-4, 8-11, 13-14, and 28-43 and that claims 1-4, 8-11, 13-14, and 28-43 be allowed. Likewise, Applicant respectfully requests consideration and allowance of new claims 44-53. Finally, Applicant respectfully requests that the Examiner reconsider and withdraw the restriction requirement of the above-identified application concerning the claims of the above-identified application that the Examiner has placed in Groups I, II, and III. The Examiner is invited to contact Applicant's below-named attorney to discuss any aspect of the above-identified application and advance this application to allowance.

Respectfully submitted,

KINNEY & LANGE, P.A.

Date: 10-16-01

By 
Philip F. Fox, Reg. No. 38,142
THE KINNEY & LANGE BUILDING
312 South Third Street
Minneapolis, MN 55415-1002
Telephone: (612) 339-1863
Fax: (612) 339-6580



TECH CENTER 1600/2900

OCT 24 2001

RECEIVED

**APPENDIX:
MARKED UP VERSION OF CLAIM AMENDMENTS**

New claims 44-53 are added as follows:

- 44. A method of enhancing the weight percent of true protein in milk produced by a ruminant, the method comprising:
providing a feed that comprises a ruminally-protected sugar alcohol; and
supplying the sugar alcohol to the abomasum of the ruminant.--
- 45. A method of enhancing the weight percent of lactose in milk produced by a ruminant, the method comprising:
providing a feed that comprises a ruminally-protected sugar alcohol; and
supplying the sugar alcohol to the abomasum of the ruminant.--
- 46. A method of enhancing the weight percent of fat in milk produced by a ruminant, the method comprising:
providing a feed that comprises a ruminally-protected sugar alcohol; and
supplying the sugar alcohol to the abomasum of the ruminant.--
- 47. A method of enhancing the weight percent of total solids in milk produced by a ruminant, the method comprising:
providing a feed that comprises a ruminally-protected sugar alcohol; and
supplying the sugar alcohol to the abomasum of the ruminant.--
- 48. A method of enhancing the weight percent of true protein, lactose, fat, total solids, or any combination of any of these in milk produced by a ruminant, the method comprising:
providing a feed that comprises a ruminally-protected sugar alcohol; and
supplying the sugar alcohol to the abomasum of the ruminant.--
- 49. A method of feeding a ruminant, the method comprising:
providing a feed that comprises a ruminally-protected sugar alcohol; and
supplying the sugar alcohol to the abomasum of the ruminant, the sugar alcohol effective to enhance the weight percent of true protein in milk produced by the ruminant.--
- 50. A method of feeding a ruminant, the method comprising:
providing a feed that comprises a ruminally-protected sugar alcohol; and
supplying the sugar alcohol to the abomasum of the ruminant, the sugar alcohol effective enhance to the weight percent of lactose in milk produced by the ruminant.--

**APPENDIX:
MARKED UP VERSION OF CLAIM AMENDMENTS**

- 51. A method of feeding a ruminant, the method comprising:
providing a feed that comprises a ruminally-protected sugar alcohol; and
supplying the sugar alcohol to the abomasum of the ruminant, the sugar alcohol
effective to enhance the weight percent of fat in milk produced
by the ruminant.--
- 52. A method of feeding a ruminant, the method comprising:
providing a feed that comprises a ruminally-protected sugar alcohol; and
supplying the sugar alcohol to the abomasum of the ruminant, the sugar alcohol
effective to enhance the weight percent of total solids in milk
produced by the ruminant.--
- 53. A method of feeding a ruminant, the method comprising:
providing a feed that comprises a ruminally-protected sugar alcohol; and
supplying the sugar alcohol to the abomasum of the ruminant, the sugar alcohol
effective to enhance the weight percent of true protein, lactose,
fat, total solids, or any combination of any of these in milk
produced by the ruminant.--